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Dated: January 25, 2005

Signature: \_\_\_\_\_

(Marcus J. Millet)

Docket No.: TRANS 3.0-038A  
(PATENT)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Harhen et al.

Application No.: 09/904,963

Filed: July 13, 2001

For: ENERGY APPLICATION WITH  
INFLATABLE ANNULAR LENS

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: Group Art Unit: 3737  
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: Examiner: E. Mantis-Mercader  
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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

RESPONSE

Dear Sir:

The present communication is responsive to the non-final Official Action mailed August 25, 2004. A petition for a two-month extension of the term for response to said Official Action, to and including January 25, 2005, is transmitted herewith.

The indication in the Official Action that the prior rejections based upon prior art and double patenting grounds have been withdrawn is greatly appreciated.

Claims 1-12 now stand rejected under 35 U.S.C. § 103(a) as obvious over *O'Connor*, U.S. Patent 6,398,792 ("*O'Connor* '792") in view of *Viebach*, U.S. Patent 5,240,005 ("*Viebach* '005"). Reconsideration and withdrawal of this rejection are earnestly solicited. Applicants' claims were previously rejected on *O'Connor* '792 alone. (6/4/04 Official Action, ¶¶ 8, 9.) In response to the Official Action of June 4, 2004, applicants previously pointed out why it would be improper

to characterize the inflated balloon (e.g., 22, Fig. 3) in O'Connor '792 as a "lens" (12/4/03 Response at 7 *et seq.*), and the rejection based upon O'Connor '792 alone with withdrawn in favor of new grounds of rejection (2/26/04 Official Action). Briefly, as previously pointed out by applicants, one of ordinary skill in the art perusing O'Connor '792 would not be lead to believe that the balloon 22 constitutes a "lens" having a "refractive surface," because (1) O'Connor '792 offers not the slightest suggestion that the shape of the circumferential wall of the balloon (the alleged refractive surface) has any effect at all in focusing; (2) the particular shape depicted in the drawings of O'Connor '792 (a cylindrical shape surrounding a cylindrical emitter) would not, in fact, serve as a refractive surface at all; and (3) O'Connor '792 offers not the slightest indication that the medium inside the balloon (an aqueous liquid containing a radiologic contrast agent) could or should have acoustic properties different from the acoustic properties of the substantially aqueous tissues disposed outside of the balloon, as would be necessary for the balloon to serve as a refractive interface.

It is not clear from the Official Action whether or not the Examiner still contends that O'Connor '792, in and of itself, teaches using the balloon as a refractive element or lens. Thus, at page 2 of the Official Action, O'Connor '792 is described as teaching "an inflatable lens having a refractive surface extending around the central axis . . . ," but at page 3, the Official Action concedes that "O'Connor '792 does not explicitly state that the ultrasonic energy is focused by the inflatable balloon." Applicants agree with the latter statement. There is, thus, no reason to characterize O'Connor '792's balloon as including "an inflatable lens having a refractive surface . . . ." O'Connor '792 merely teaches a balloon, and not a lens.

*Viebach* '005 teaches a generally disk-shaped ultrasonic lens having a central axis 17 (Fig. 1A; col. 4, ln. 47) overlying a flat disk-like "sound source 7" (Fig. 1A; col. 3, ln. 9) in an extracorporeal device, i.e., an ultrasonic lithotripsy unit intended to be positioned outside of the patient's body ultrasonically coupled to the patient's body by a "coupling surface 5." (See col. 3, lns. 8-9; col. 1, lns. 6 et seq.) As the Examiner is doubtless aware, ultrasonic lithotripsy, or as *Viebach* '005 states it, "focusing of ultrasonic and shock waves for the non-contact crushing of a concretement disposed in the body of a living being," is commonly performed by applying ultrasound from outside of the body into the kidneys to break up kidney stones. It employs transducers many centimeters in diameter in contrast to the tiny catheter-borne ultrasonic transducers of *O'Connor* '792.

The asserted teaching in *Viebach* '005 that media of different acoustic velocities can serve as a focusing structure in a lens would not appear relevant to a person of ordinary skill in the art starting from *O'Connor* '792, inasmuch as *O'Connor* '792 does not incorporate a lens of any type and does not suggest that a lens would be beneficial in its structure. Further, the asserted motivation to combine *Viebach* '005 with *O'Connor* '792 because it "provides a focusing device with a wide range of focal lengths and reduces technical expenditures" would be irrelevant to a person of ordinary skill in the art attempting to implement the *O'Connor* '792 invention. First, nothing in *O'Connor* '792 has been pointed out as suggesting that a variable focal length would be desirable in its structure or use. The lack of motivation is particularly egregious, because the references deal with transducer assemblies for entirely different purposes used in entirely different environments. Second, *O'Connor* '792's suggestion that its structure "reduces the technical expenditures in the case of therapy instruments"

must be understood in the context in which it is offered, namely, that the *Viebach* '005 device reduces technical expenditures vis-à-vis other arrangements for providing an adjustable focus in an extracorporeal ultrasonic lithotripsy device. A person of ordinary skill in the art would not fairly infer from *Viebach* '005 that *Viebach* '005's arrangement provides reduced "technical expenditures" vis-à-vis the simple balloon arrangement of *O'Connor* '792.

But even if a person of ordinary skill in the art were somehow motivated to look at *Viebach* '005 for teachings which might be potentially useful in *O'Connor*'s structure, he would be taught by *Viebach* '005 that ultrasonic lenses should be fabricated as generally disk-like structures overlying similarly disk-like transducers. If one skilled in the art were somehow motivated to attempt the daunting task of using teachings from *Viebach* '005's extracorporeal transducer in the entirely different environment of a miniature, intravascular system, he would be lead by *Viebach* '005 to provide one or more lenses and transducers as taught by *Viebach* '005. Nothing in either reference fairly suggests that an annular structure surrounding a cylindrical transducer can serve as a lens, or that any benefit is to be gained by such an arrangement. Thus, the combined references would not lead to a structure as recited in claim 1, or to a method as recited in independent claim 9.

As previously pointed out, dependent claim 10 specifically recites a method of operation in which ultrasonic energy is refracted and concentrated into a band of relatively small axial extent and additionally refracted after such concentration so that the energy propagates, after such additional refraction step, substantially radially. This action is exemplified in Fig. 5 of the drawings, and was further explained in the Amendment filed December 4, 2003. (See pp. 10-11.) Nothing in either *O'Connor* '792 or *Viebach* '005 has

been pointed out as suggesting such a step, and accordingly, the rejection of claim 10 must be withdrawn for this additional reason as well.

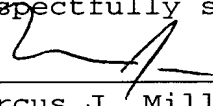
Favorable reconsideration and allowance of all claims in the application are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that she telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which she might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: January 25, 2004

Respectfully submitted,

By   
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